REMARKS

Claims 1-31 are pending in this application. Claims 17, 20, and 26 are amended to explicitly include the elements recited in claims 14, 19, and 23, respectively.

CLAIM OBJECTIONS

Claims 17, 20, and 26 were objected to as allegedly being of improper dependent form. Without conceding to the propriety of this objection, claims 17, 20, and 26 are canceled in order to expedite prosecution of this application.

REJECTIONS UNDER § 102

Claims 1-5 and 7-31 were rejected under § 102(b) as allegedly being anticipated by U.S. Patent No. 6,178,349 (Kieval) in combination with U.S. Patent No. 5,344,438 (Testerman et al.). Applicants respectfully request reconsideration of this rejection.

As an initial matter, Applicants respectfully point out that a rejection under § 102 requires that all the claim elements be taught in a single reference. *See* MPEP 2131.01. Although *Kieval* incorporates *Testerman* by reference, Applicants contend that this rejection using both *Kieval* and *Testerman* is improper. However, without conceding to the propriety of this rejection and in order to expedite the prosecution of this application, Applicants submit that neither *Kieval* nor *Testerman* anticipate the claimed inventions.

Claims 1-5 and 7-13

Independent claim 1 recites a delivery device comprising a "first series of flexibly connected delivery contacts, wherein a leading delivery contact of the first series of flexibly connected delivery contacts is engagably associated with a trailing delivery contact of the first series of flexibly connected delivery contacts in an operative position of the delivery device." Furthermore, independent claim 1 also recites a second series of flexibly connected delivery contacts having this same configuration.

As indicated in the specification, "'engagably associated' is generally meant that leading delivery contact 20a and trailing delivery contact 20d are associated with each other, although not necessarily contacting each other, such that the respective series to which they belong form a

secure elliptical or circular configuration in an operative position of device 10"[1] (emphasis added).

The Office Action asserts that nerve stimulators 92 and 94 in FIG. 1 of *Kieval* correspond to the first and second series of delivery contacts recited in claim 1. Without conceding that these nerve stimulators 92 and 94 actually correspond to a first and second series of delivery contacts, Applicants point out that FIG. 2 of *Kieval*, which shows one of the nerve stimulators in more detail, reveals that electrode 116 of the nerve stimulators does not "form a secure elliptical or circular configuration" when electrode 116 is in an operative position. Thus, electrode 116 does not have a leading delivery contact and a trailing delivery contact that are "engagably associated" with each other, as required by claim 1.

The Office Action also asserts that the plurality of button electrodes 62-86 in the cuff electrode 60 shown in FIG. 3 of *Testerman* correspond to the first and second series of delivery contacts recited by claim 1. Without conceding that these button electrodes actually correspond to a first and second series of delivery contacts, Applicants point out that these button electrodes do not "form a secure elliptical or circular configuration" when they are in an operative position. Therefore, these button electrodes in *Testerman* do not have a leading delivery contact and a trailing delivery contact that are "engagably associated" with each other.

For at least these reasons, Applicants respectfully submit that claims 1-5 and 7-13 are not anticipated by either *Kieval* or *Testerman*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

Claims 14-18

Independent claim 14 recites an assembly for stimulating ganglia comprising a "first probe insertable in a ganglion" and a "second probe insertable in a ganglion." For example, referring to the embodiment shown in FIG. 14, neurostimulation assembly 200 has a first probe 210a and a second probe 210b that are designed to be insertable in a ganglion.[2]

Unlike the invention of claim 14, neither *Kieval* nor *Testerman* teach a probe that is "insertable in a ganglion." *Kieval* indicates that the medical device is for stimulating a nerve,[3] not a ganglion. Furthermore, *Kieval* has no teaching of a probe that is "insertable" in a tissue

[1] Specification, pg. 7, lns. 27-32.
[2] Specification, pg. 12, lns. 15-30.
[3] *Kieval*, Abstract.

structure. For example, FIG. 2 shows the base 118 of electrode 116 having "a cuff configuration so as to be wrapped about the nerve 64."[4] Likewise, *Testerman* indicates that the electrode is for "mounting on a nerve,"[5] not insertable in a ganglion.

For at least these reasons, Applicants respectfully submit that claims 14-18 are not anticipated by either *Kieval* or *Testerman*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

Claims 19-22

Independent claim 19 recites an assembly for stimulating ganglia comprising the following features:

(i) an axially elongated shaft;

(ii) a first terminal member that is slidably engagable with the outer surface of the shaft;

(iii) the proximal end of the first terminal member having a generally concave configuration and adjacently positionable to a ganglion;

(iv) a second terminal member having these same features.

For example, referring to the embodiment shown in FIG. 17, neurostimulation assembly 200 has a shaft 170.[6] First and second terminal members, 280a and 280b, are slidably engagable with the outer surface 180 of shaft 170. Each terminal member, 280a and 280b, has a generally concave configuration such that it is adjacently positionable to a ganglion 300.

Unlike the invention of claim 19, neither *Kieval* nor *Testerman* teach a combination of these features. The Office Action asserts that leads 96 and 98 in FIG. 1 of *Kieval* correspond to an axially elongated shaft, in which cuff-like electrode body 112 is slidable. Without conceding that leads 96 and 98 actually correspond to an axially elongated shaft, and without conceding that electrode body 112 actually corresponds to a first or second "terminal member," there is no indication that the electrode body 112 is "slidably engagable" with leads 96 and 98. In fact, an electrode is conventionally fixed to an electrode lead, not slidable in relation to the electrode, and nothing in *Kieval* indicates otherwise.

Furthermore, unlike the invention of claim 19, the electrode body 112 in *Kieval* is not "adjacently positionable to a ganglion." As explained above, FIG. 2 of *Kieval* shows the base

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[4] *Kieval*, col. 5, lns. 48-50.
[5] *Testerman*, Abstract.
[6] Specification, pg. 13, ln. 30 – pg. 14, ln. 8.

118 of electrode 116 as having "a cuff configuration so as to be wrapped about the nerve 64." Likewise, as explained above, *Testerman* indicates that the electrode is for "mounting on a nerve." Both physiologically and anatomically, ganglia are nervous system structures that are distinct from nerves. For example, nerves generally have an elongated cylindrical shape (e.g., the nerve 64 of *Kieval*), whereas ganglia generally have a bulbous shape (e.g., ganglion 300 shown in FIG. 17 of the present application).

For at least these reasons, Applicants respectfully submit that claims 19-22 are not anticipated by either *Kieval* or *Testerman*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

Claims 23-27

Independent claim 23 recites an assembly for stimulating ganglia comprising the following features:

(i) an axially elongated shaft;

(ii) a first delivery structure slidably engagable with the outer surface of the shaft;

(iii) a second delivery structure slidably engagable with the outer surface of the shaft.

For the same reasons explained above with respect to the first and second terminal members that are slidably engagable to a shaft, neither *Kieval* nor *Testerman* teaches delivery structures that are slidably engagable to a shaft. For at least these reasons, Applicants respectfully submit that claims 23-27 are not anticipated by either *Kieval* or *Testerman*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

Claims 28-31

Independent claim 28 recites a method of stimulating a ganglion involving the step of "encasing a delivery device around at least a portion of a ganglion." Independent claim 30 recites a method of stimulating sympathetic ganglia involving "placing the first ganglion stimulator adjacent to a first ganglion."

As explained above, the devices of *Kieval* and *Testerman* are designed for use with nerves, not ganglia; and any methods described in these references are with respect to stimulating nerves, not ganglia. For at least these reasons, Applicants respectfully submit that

claims 28-31 are not anticipated by either *Kieval* or *Testerman*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

REJECTIONS UNDER § 102/103

Claim 5 was rejected as allegedly being anticipated under § 102(a), or alternatively, being rendered obvious under § 103(a) by *Kieval*. Applicants respectfully request reconsideration of this rejection.

The device of claim 5 has three series of flexibly connected delivery contacts, with each series having four delivery contacts. For example, referring to the embodiment shown in FIG. 13, device 10a has three series of flexibly connected delivery contacts, each with four delivery contacts (20a-20d). As explained in the specification,[7] the number of delivery contacts in each series can depend upon characteristics of the ganglion to be stimulated, which in turn relates to characteristics of the patient (e.g., age, height, or gender) as well as the type of ganglion. A device having three series of flexibly connected delivery contacts, with each series having four delivery contacts, is particularly useful in certain patients and/or certain ganglia.

Kieval does not teach a device having these features. Further, there is no reason to modify *Kieval* to have three series of flexibly connected delivery contacts, with each series having four delivery contacts. The electrode of *Kieval* is designed for use with nerves, not ganglions, and as such, *Kieval* has no need for this particular arrangement of delivery contacts.

For at least these reasons, Applicants submit that claim 5 is both novel and non-obvious over *Kieval*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

REJECTIONS UNDER § 103

Claim 6 was rejected under § 103(a) as allegedly being rendered obvious by *Kieval*. Applicants respectfully request reconsideration of this rejection.

The device of claim 6 has three series of flexibly connected delivery contacts, with the diameter of the third series being greater than the diameter of the first and second series. For example, referring to the embodiment shown in FIG. 4, delivery device 10 has three series of

[7] Specification, pg. 8, ln. 29 – pg. 9, ln. 17.

flexibly connected delivery contacts: a first series (top), a second series (bottom), and a third series (middle).[8] The third series has a larger diameter than the first series and second series. This allows device 10 to form "a substantially ovoid configuration to conform to the configuration of a ganglion."[9]

As explained above, the cylindrically-shaped electrode of *Kieval* is designed for use with nerves. Without a need to form "a substantially ovoid configuration to conform to the configuration of a ganglion," there is no reason to modify the *Kieval* electrode to have three series of flexibly connected delivery contacts with the third series having a larger diameter than the first and second series.

For at least these reasons, Applicants submit that claim 6 is non-obvious over *Kieval*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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[8] Specification, pg. 7, lns. 21-32.
[9] Specification, pg. 7, lns. 23-24.